OAto Bock

Summary of Safety and Effectiveness STIWELL med4

108013

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QUALITY FOR LIFE

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C Product Name/ Classification Name:

Common or Usual Name:

Powered Muscle Stimulator

Proprietary or Trade Name:

STIWELL med4

Model Number:

900101S

Class	Regulation No.	Device Classification Name	Product	Speciality
			Code	
II	890.5850	Stimulator, Muscle, Powered	IPF	Physical Medicine
TI T	882.5890	Stimulator, Nerve,	GZJ	Neurology
		Transcutaneous, For Pain Relief		
II.	882.5050	Device, Biofeedback	HCC	Neurology
Н	882.5810	Stimulator, Neuromuscular,	GZI	Neurology
		External Functional		
Н	876.5320	Stimulator, Electrical, Non-	' KPI	Gastroenterology/
		Implantable, For Incontinence		Urology



D Predicate Devices:

510(k) No.	Predicate Device	Manufacturer	Regulation Number	Product Code(s)	Clearance Date
K032954	Elpha Models II 500, II 1000, II 2000, II 3000 A	Danmeter A/S	890.5850	IPF, GZJ	08/09/2004
K053434	Myotrac Infinity Electrical Stimulator	Thought Technology Ltd.	876.5320	KPI, HCC, IPF	03/15/2006
K040849	Mentamove	Cole & Associates	890.5850	IPF, HCC	10/01/2004
K940301	Compex 2	Biodex Medical Systems, Inc.	890.5850	IPF, GZJ	12/28/1994
K032988	Elpha 4 Conti	Danmeter A/S	876.5320	KPI	12/03/2003
K031900	Handmaster	Ness- Neuromuscular Electrical Stimulation Systems	882.5810	GZI	08/08/2003

E Description:

The STIWELL med4 is powered by rechargeable batteries. It has four stimulation channels and two EMG measurement channels.

The STIWELL med4 is intended for stationary use in a hospital as well as home use by the patient. The physician/therapist has the flexibility to adjust the programs and monitors the progress of the therapy. Statistics regarding the completed treatments can be retrieved from the STIWELL med4 and from the PC.

In order to gain a proper understanding of STIWELL med4, it is important to read the manual before beginning to use the STIWELL med4.



F **Substantial Equivalence:**

Powered Muscle Stimulator:

Characteristics/ Specific.	New Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Basic Unit Chracteristics	NEW DOORS		· ·		
510(k) Number	K080950	K032954	K053434	K040849	K940301
Manufacturer	Otto Bock	Danmeter A/S	Thought Technology Ltd.	Mentamove North America, LCC	Compex SA
Device Name, Model	STIWELL med4	Elpha II3000	Myotrac Inlinity	Mentamove	Compex 2
Power Source(s)	Battery Pack Li-lon † 1,1V	Battery NMH or Alkaline 9V	Battery Pack N:MH rechargeable	Battery Pack NiMH rechargeable	Battery Pock NiMH 7,2 V
Method of Line Current (solution	Medical Class II Power Adapter – Mascat (12,6VDC-15,1W)	N/A	Medical Class II Power Adapter (6VDC-15W)	Battery Charger (6VDC- 2,1W)	Bottery Charger (11VDC- 7,2VV)
Patient Leakage Current (normal condition)	N/A (Battery)	N/A (Battery)	N/A (Battery)	N/A (Battery)	N/A (Bottery)
Patient Leakage Current (single fault condition)	N/A (Battery)	N/A (Battery)	N/A (Battery)	N/A (Bottery)	N/A (Bottery)
Number of Output Modes	1	1	1	11	1
Number of Output Channels Number of EMG (input)	4 .	2	2	1	4
Chonnels	2	N/A	2	1	N/A
EMG sensitivity EMG Sampling Rate	tµV 3kHz	N/A N/A	<0.1µV 2,048kHz	1µV Unknown	N/A N/A
EMG detection (bipoer/			1		N/A
monopolar)	Bipolar	N/A	Bipolor	Bipolar 2-2000uV	
EMG range (µV) EMG bandwidth	1-2000μV 70-480Hz	N/A N/A	0-2000μV 10Hz-1kHz	2-2000µV Unknown	N/A N/A
EMG signal processing (eg.	AVR	N/A	RMS	Unknown	N/A
RMS)	(Average Rectried Value)		(Root Mean Square)		
Synchronous or Alternating?	Alternating Transformer, Inductive	Unknown	Alternoting	N/A	Synchronous
Method of Channel Isolation	couplers	Unknown	Unknown	Unknown	Transformer
Regulated Current or Regulated Voltage?	Regulated Current	Regulated Current	Regulated Current	Regulated Current	Regulated Current
Software/Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes
PC Software?	Yes	No	Yes	No	No
Automatic Overload Trip?	Yes	YB\$	Yes	Yes	Yes Yes
Automatic Na-Load Trip? Automatic Shut Off?	Yes Yes (10min)	Yes Yes	Yes Unknown	Yes Unknown	Unknown
Patient Override Control?	Yes (Stop Button)	Yes	Yes	Yes	Yes
Indicator Display: On/Off	Yes	Yea	Yes	Yes	Yes
Status? Indicator Display: Low Batt.?	Yes	Yes	Yes	Yes	Yes
Indicator Display:	Yes	Yes	Yes	Yes	Yes
Voltage/Current Level?					
Timer Range [minutes]	2 – 120min (EC 6060)-1	5 - 95min and cont. IEC 80601-1	1 – 120min	Unknown	3 – 64min
Compliance with Voluntary Standards? (if yes, specify)	IEC 60801-1-2	IEC 60601-1-2	Unknown	Unknown	Unknown
	100 40001 0 10	UCC 90901 0 10	Jane Company	UII KIIO MA	=
	IEC 60601-2-10 Yes	IEC 60601-2-10			Unknown
Compliance with 21 CFR 898? Weight	Yes 440g	Unknown 158g	Unknown 330g	Unknown Unknown	Unknown 420g
Compliance with 21 CFR 898? Weight Dimensions (WxHtiD) in [mm]	Yes 440g 175x95x30	Unknown 158g 114x80x31	Unknown 330g 102x152x51	Unknown Unknown Unknown	420g 148x80x30
Compliance with 21 CFR 898? Weight Dimensions (WxHtiD) in [mm] Housing Moternal and Constr.	Yes 440g	Unknown 158g	Unknown 330g	Unknown Unknown	420g
Compliance with 21 CFR 898? Weight Dimensions (WxHtiD) in [mm]	Yes 440g 175x95x30	Unknown 158g 114x80x31 Plastics Biphasia asymmetrical	Unknown 330g 102x152x51 Plastics Biphosic asymmetrical	Unknown Unknown Unknown Plastics Biphasic symmetrical	420g 148x80x30 Aluminum Biphosic symmetrical
Compliance with 21 CFR 898? Weight Dimensions (WartsD) in [mm] Housing Moternal and Constr. Output Specifications Waveform Shape	Yes 440g 175x95x30 Plostica	Unknown 158g 11486x31 Plastics	Unknown 330g 102x152x51 Plastics	Unknown Unknown Unknown Plastics	420g 148x80x30 Aluminium
Compliance with 21 CFR 898? Weight Dimensions (WithD) in [mm] Housing Moterial and Constr. Output Specifications Worelorm Shape Maximum Output Votage (5000)	Yes 440g 175x95x30 Plostics Biphosic symmetrical	Unknown 158g 114x80x31 Plastics Biphasia asymmetrical	Unknown 330g 102x152x51 Plastics Biphosic asymmetrical	Unknown Unknown Unknown Plastics Biphasic symmetrical	420g 148x80x30 Aluminum Biphasic symmetrical
Compliance with 21 CFR 898? Whight Dimensions [WithD] in [mm] Housing Motand and Constr. Output Specifications Worelorm Shope Macmum Output Votage (5000) Mammum Output Votage (200)	Yes 440g 175:95:930 Plostics Biphosic symmetrical Rectangular	Unknown 158g 114490x31 Plastics Plastics Biphasic asymmetrical Reclangular with discharge	Unknown 339g 102x152x51 Plastics Biphose asymmetrical Rectangular with discharge	Unknown Unknown Unknown Plastics Biphasic symmetrical Rectangular	420g 148360x30 Aluminum Biphasic symmetrical Rectangular, Trioniquiar
Compliance with 21 CFR 898? Weight Demensions (WartaD) in [mm] Housing Motional and Constr. Output Specifications Worelorm Shape Mazmum Output Votage (5000) Mazmum Output Votage (2\text{(2})) Mazmum Output Votage (2\text{(3})) Mazmum Output Votage	Yes 440g 175:95:30 Plostica Biphosic symmetrical Rectangular 50V	Unknown 158g 1145933 Postics Postics Biphosic asymmetrical Rectorge/or with discharge 50V	Unknown 330g 102x152x51 Plastics Biphase asymmetrical Rectangular with discharge 50V	Unknown Unknown Unknown Plastos Biphase symmethical Rectangular Unknown	420g 148360x30 Alumnum Bryhass symmetrical Rectongular, Triongular 50V
Compliance with 21 CFR 898? Winght Dimensions (WarbD) in [mm] Housing Motiand and Constr. Output Specifications Worelorm Shope Mozimum Output Votoge (5000) Mozimum Output Votoge (2X0) Mozimum Output Votoge (2X0)	Yes 440g 175:69:30 Plostica Biphosic symmetrical Rectargular 50V	Unknown 158g 11450x31 Pleates Biphose asymmetrical Rectangular with discharge 50V 164V	Unknown 330g 102x152x51 Plastics Biphose asymmetrical Rectangular with discharge 50V Unknown	Unknown Unknown Unknown Unknown Plastics Biphase symmethical Risctangular Unknown Unknown	420g 148s90x30 Abummum Biphase symmetricol Rectorgular, Triongular 50V
Compliance with 21 CFR 898? Whight Dimensions (WithD) in [mm] Housing Motand and Constr. Output Specifications Worelorm Shope Macamum Output Votage (5000) Macamum Output Votage (28.0) Macamum Output Votage (19.50) Macamum Output Votage (19.50) Macamum Output Current (5000)	Yes A40g 175:95:30 Postica Biphasic symmetrical Rectangular 50V 115V N/A	Unknown 158g 11450x31 Ploates Biphosic daymentrical Rectangular with dacharge 50V 184V Unknown	Unknown 330g 102x152x51 Plastes Biphose asymmetrical Rectangular with discharge 50V Unknown Unknown	Unknown Unknown Unknown Unknown Plastos Biphase symmetrical Rectangular Unknown Unknown	420g 148x90x30 Abunnaun Biphasic symmetricol Rectorgular, Trongular 50V 200V N/A ^{G1}
Compliance with 21 CFR 898? Weight Weight Demensions (WartaD) in [mm] Houseig Moterial and Constr. Output Specifications Worwlorm Shape (5000) Mosmum Output Votage (5000) Mosmum Output Votage (24.0) Mosmum Output Votage (19.50) Mosmum Output Votage (19.50) Mosmum Output Votage (19.50) Mosmum Output Current (5000)	Yes A40g 175:05:30 Plostica Biphosic symmetrical Rectangular 50V 115V N/A 100mA	Unknown 158g 114s50x31 Plostocs Biphosic caymentricol Recrongulor with dischorge 50V 164V Unknown 100mA	Unknown 330g 102x152x51 Plastes Plastes Biphose osymmetrical Rectangular with discharge 50V Unknown Unknown	Unknown Unknown Unknown Plastes Biphase symmetrical Rectangular Unknown Unknown Unknown Unknown	420g 148s80s30 Abummum Buphasic symmetricol Rectorgulor, Trionigular 50V 200V N/A G1 100mA
Compliance with 21 CFR 898? Weight Demensions (WartaD) in [mm] Housen Moternal and Constr. Output Specifications Worelorm Mazmum Output Votage (5000) Masmum Output Votage (2k3) Masmum Output Votage (10k3) Masmum Output Current (5000) Mosmum Output Current (5000) Mosmum Output Current (10k3) Mosmum Output Current (10k3) Mosmum Output Current (10k1) Mosmum Output Current (10k1) Mosmum Output Current (10k1) Mosmum Output Current	Yes 440g 175:95:30 Postics Biphosic symmetrical Rectargular 50V 115V N/A 100mA 58mA N/A 50µs - 400µs	Unknown 158g 114s50x31 Plastics Biphosic osymmetricol Rectorigulor with discharge 50V 164V Unknown 100mA 82mA Unknown 100ps = 400ps	Unknown 330g 102x152x51 Plastics Biphose osymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown	Unknown Unknown Unknown Unknown Plastics Biphases symmetrical Rectangular Unknown Unknown Unknown Unknown Unknown Unknown Unknown	420g 148s80x30 Abummum Biphase symmetricol Rectorgular, Transgular 50V 200V N/A ^{G1} 100mA 100mA N/A 15µs – 999µs
Compliance with 21 CFR 868? Whight Whight Dimensions (Warbd) in [mm] Housing Motional and Constr. Output Specifications Worestorm Shope Mozimum Output Vottoge (5000) Mozimum Output Vottoge (2\C) (19\C) Mozimum Output Vottoge (19\C) (19\C) Mozimum Output Current (5000) Mozimum Output Current (5000) Mozimum Output Current (10\C) (10\C) Mozimum Output Current (10\C) (10\C) Pulse Width (specify units) Frequency (Hr)	Yes A40g 175s95s30 Plostics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 50 ₁₅ - 400 ₁₅ 1 - 140hz	Unknown 158g 114x50x31 Plastes Biphosic caymentrical Rectangular with discharge 55V 164V Unknown 100mA B2mA Unknown 100us = 400us 2 = 100ts	Unknown 330g 102x152x51 Plastes Biphose asymmetrical Rectongular with discharge 50V Unknown Unknown 100mA Unknown Unknown Unknown 50jis-400jis 2 - 100Hz	Unknown Unknown Unknown Unknown Plastos Biphase symmetrical Rectangular Unknown Unknown Unknown Unknown Unknown Unknown 320µa 3,1kHz GF, 33Hz AMF	420g 148180x30 Abummum Brphase symmetricol Rectorgulor, Triongulor 50V 200V N/A G1 100mA 100mA N/A 15µs 999µs 1 200Hr
Compliance with 21 CFR 898? Weight Demensions (WartaD) in [mm] Housen Moternal and Constr. Output Specifications Worelorm Mazmum Output Votage (5000) Masmum Output Votage (2k3) Masmum Output Votage (10k3) Masmum Output Current (5000) Mosmum Output Current (5000) Mosmum Output Current (10k3) Mosmum Output Current (10k3) Mosmum Output Current (10k1) Mosmum Output Current (10k1) Mosmum Output Current (10k1) Mosmum Output Current	Yes 440g 175:95:30 Postics Biphosic symmetrical Rectargular 50V 115V N/A 100mA 58mA N/A 50µs - 400µs	Unknown 158g 114s50x31 Plastics Biphosic osymmetricol Rectorigulor with discharge 50V 164V Unknown 100mA 82mA Unknown 100ps = 400ps	Unknown 330g 102x152x51 Plastics Biphose osymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown	Unknown Unknown Unknown Unknown Plastics Biphases symmetrical Rectangular Unknown Unknown Unknown Unknown Unknown Unknown Unknown	420g 148s90x30 Abummum Biphase symmetricol Rectorgular, Transgular 50V 200V N/A ^{G1} 100mA 100mA N/A 15µs – 999µs
Compliance with 21 CFR 898? Weight Weight Demenations (WartaD) in [mm] Housing Motional and Constr. Output Specifications Wowelform Marmum Output Votage (5000) Marmum Output Votage (24.0) Marmum Output Votage (24.0) Marmum Output Votage (10.50) Marmum Output Current (5000) Mozimum Output Current (24.0) Mozimum Output Current (24.0) Mozimum Output Current (24.0) Mozimum Output Current (10.40) Pulse Width (specify units) Frequency [Hz] Fre on interferental modes only:	Yes A40g 175s95s30 Plostics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 50 ₁₅ - 400 ₁₅ 1 - 140hz	Unknown 158g 114x50x31 Plastes Biphosic caymentrical Rectangular with discharge 55V 164V Unknown 100mA B2mA Unknown 100us = 400us 2 = 100ts	Unknown 330g 102x152x51 Plastes Biphose asymmetrical Rectongular with discharge 50V Unknown Unknown 100mA Unknown Unknown Unknown 50jis-400jis 2 - 100Hz	Unknown Unknown Unknown Unknown Plastos Biphase symmetrical Rectangular Unknown Unknown Unknown Unknown Unknown Unknown 320µa 3,1kHz GF, 33Hz AMF	420g 148s90x30 Abummum Brphase symmetricol Rectorgulor, Triongulor 50V 200V N/A d1 100mA 100mA N/A 15µs 999µs 1 200Hr
Compliance with 21 CFR 898? Weight Weight Dimensions (WartsD) in [mm] Housing Motiand and Constr. Output Specifications Woovelorm Shape Mazamum Output Votage (5000) Marimum Output Votage (10.02) Marimum Output Votage (10.02) Marimum Output Votage (10.02) Marimum Output Current (5000) Marimum Output Current (20.0) Pulse Worth (specify units) Frequency [tri] For interferential modes only: Beal Frequency [tri] For multiphose waveforms only: Symmetrical phoses? For multiphose waveforms	Yes 440g 175x95x30 Plostica Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 50µ4 - 400µ4 1 - 140Hz N/A	Unknown 158g 114x50x31 Plastics Biphosic caymentricol Rectorgulor with discharge 50V 164V Unknown 100mA B2mA Unknown 100ys = 400ys 2 - 100Hz N/A	Unknown 330g 102x152x51 Plastics Biphose osymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown Unknown 50µs – 400µs 2 – 100Hz N/A	Unknown Unknown Unknown Unknown Plastics Biphase symmetrical Rectangular Unknown Unknown Unknown Unknown Unknown Unknown 320ja 3,1414; GF, 3314 AMF	420g 148s90x30 Abummum Biphasic symmetricol Rectorgular, Troniquiar 50V 200V N/A ^{G1} 100mA 100mA 15µa - 999µs 1 - 200Hz N/A
Compliance with 21 CFR 868? Weight Weight Dimensions (WarbD) in [mm] Houseg Moterial Constr. Output Specifications Worelform Shope (5000) Mosmum Output Votage (5000) Mosmum Output Votage (1040) Mosmum Output Votage (1040) Mosmum Output Votage (1040) Mosmum Output Current (5000) Mosmum Output Current (6000) Mosmum Output Current (1040) Pulse Width (specify units) Frequency (Hz) For interferential modes only: Beat Prequency (Hz) For interferential modes only: Beat Prequency (Hz) For multiprisone waveforms only: Symmetrical phoses or	Yes	Unknown 158g 114:50x31 Plostoca Biphosic caymentricol Rectiongdor with dischorge 50V 184V Unknown 100mA 82mA Unknown 100µs = 400µs 2 = 100µs N/A N/A	Unknown 330g 102x 152x51 Plastics Biphose osymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown Unknown Unknown N/A	Unknown Unknown Unknown Unknown Plastos Biphase symmethical Rectangular Unknown Unknown Unknown Unknown Unknown Nuknown Nukno	420g 148:80x30 Abminium Biphasic symmetricol Rectorgular, Trongular 50V 200V N/A ^{G1} 100mA 100mA 100mA N/A 15µs - 999µs 1 - 200Hz N/A N/A N/A OµC Some positive and negative
Compliance with 21 CFR 868? Weight Weight Dimensions (WishbD) in [mm] Housing Motional and Constr. Output Specifications Worelorin Shopse (5000) Mosmum Output Votage (5000) Mosmum Output Votage (10\O) Mosmum Output Votage (10\O) Mosmum Output Current (5000) Mosmum Output Current (5000) Mosmum Output Current (5000) Mosmum Output Current (6000) Mosmum Output Current (6000) Frequency [Hz] For interferential modes only: Boal Frequency [Hz] For multiphosic wordoms only: Symmetrical phoses? For house Duration (including units): Nat Charge [µC] per pulse]: (5000) Mosmum Phose Charge [µC]	Yes A40g 175s95s30 Plostics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 50μs - 400μs 1 - 140Hz N/A N/A N/A N/A OμC	Unknown 158g 114s50/31 Ploatics Biphosic daymentricol Rectorgulor with dischorge 50V 164V Unknown 100mA 82mA Unknown 100ps - 400ps 2 - 100Hz N/A N/A N/A N/A OpC	Unknown 330g 102x 152x51 Plastics Biphose asymmetrical Rectangular with discharge 50V Unknown Unknown Unknown Unknown Unknown N/A N/A N/A 0µC	Unknown Unknown Unknown Unknown Plastos Biphase symmethool Rectangular Unknown Unknown Unknown Unknown Unknown Unknown Noknown Unknown Noknown	420g 148s90x30 Abuntneum Biphosic symmetricol Rectorgular, Tromqular 50V 200V N/A G1 100mA 100mA 15pa – 999pa 1 – 200Hz N/A N/A N/A N/A 0pC
Compliance with 21 CFR 868? Weight Weight Dimensions (WishbD) in [mm] Housing Motional and Constr. Output Specifications Worestorn Shopse (5000) Masmum Output Votage (5000) Masmum Output Votage (1010) Masmum Output Votage (1010) Masmum Output Votage (1010) Masmum Output Current (5000) Masmum Output Current (5000) Masmum Output Current (5000) Masmum Output Current (5001) Frequency [Hz] For interferential motios only: For multiphasic waveforms only: Symmetrical phases? For multiphasic waveforms only: Symmetrical phases Masmum Phase Charge [µC] (5000)	Yes 440g 175:95:30 Postics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 100mA 58mA N/A N/A N/A N/A N/A N/A N/A N/A OpC Some positive and negative impulse.	Unknown 158g 114s50/31 Ploatics Biphosic daymentricid Rectorgulor with dischorge 50V 164V Unknown 100mA 82mA Unknown 100m4 82mA Vinknown N/A N/A N/A N/A OµC Output capoottor	Unknown 330g 102x 152x51 Plastics Biphase asymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown A Unknown N/A N/A N/A N/A OjiC Output capacitor	Unknown Unknown Unknown Unknown Plastos Biphase symmethool Rectangular Unknown Unknown Unknown Unknown Unknown Unknown Noknown Unknown	420g 148x80x30 Abminium Biphasic symmetricol Rectorgular, Trongular 50V 200V N/A G1 100mA 100mA 100mA N/A 15pa = 999pa 1 = 200Hz N/A N/A N/A N/A OpC Same positive and negative impulse
Compliance with 21 CFR 868? Weight Weight Dimensions (WishbD) in [mm] Housing Motianal and Constr. Output Specifications Worelarm Shape Mazimum Output Votage (15002) Mazimum Output Votage (15002) Mazimum Output Votage (10102) Mazimum Output Votage (10102) Mazimum Output Current (2010) Mazimum Output Current (2010) Mazimum Output Current (1010) Pulses Width [specify units) Frequency [Hz] For interferential imposes only: Beal Frequency [Hz] For multiphosis waveforms only: Symmotrical phoses? For multiphosis waveforms only: Symmotrical phoses? For multiphosis waveforms only: Symmotrical phoses? For multiphosis waveforms only: Phose Duration (including units); Nat Charge [µC] per pulse]: (50001) Maximum Phose Charge [µC] (50001) Maximum Phose Charge [µC] (15001) Maximum Phose Density	Yes 440g 175:95:30 Postics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 100mA 58mA N/A N/A N/A N/A N/A N/A N/A N/A N/A N/	Unknown 158g 114s50/31 Ploatics Biphosic daymentricid Rectorgulor with dischorge 50V 164V Unknown 100mA 82mA Unknown 100µs = 400µs 2 = 100Hz N/A N/A N/A N/A OµC Output capoottor 40µC	Unknown 330g 102x 152x51 Plastics Biphase asymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown A Unknown Unknown N/A N/A N/A N/A OjiC Output capactor 60µC	Unknown Unknown Unknown Unknown Plastos Biphase symmethical Rectangular Unknown Unknown Unknown Unknown Unknown Unknown Noknown Unknown	420g 148x80x30 Abminium Biphasic symmetricol Rectorgular, Trongular 50V 200V N/A G1 100mA 100mA 100mA 15pa - 999pa 1 - 200Hz N/A N/A N/A N/A OpC Some posters and negative impulse 80pC
Compliance with 21 CFR 868? Weight Weight Dimensions (WishbD) in [mm] Housing Motiand and Constr. Output Specifications Woreldorm Shope Mazimum Output Votage (5000) Mazimum Output Votage (10\times) Mazimum Output Votage (10\times) Mazimum Output Votage (10\times) Mazimum Output Votage (10\times) Mazimum Output Current (5000) Mazimum Output Current (10\times) Mazimum Output Current (10\times) Mazimum Output Current (10\times) Pulse Width (specify units) Frequency [Ht] For interferential modes only: Bood Frequency [Ht] For interferential modes only: For multiphosic waveforms only: Symmetrical phoses? For multiphosic waveforms only: Symmetrical phoses? For multiphosic waveforms only: Phase Durotion (including units): Net Charge [µC] (50001) Mazimum Phose Charge [µC] (50001) Mazimum Phose Charge [µC] (50001) Mazimum Current Density (ind/cm) (50001) Mazimum Courrent Density (ind/cm) (50001) Mazimum Power Density (iv/cm) (50001) Mazimum Current Density (iv/cm) (50001)	Yes	Unknown 158g 114s60x31 Plostoc Biphosic caymentricol Rectorgulor with discharge 50V 164V Unknown 100mA B2mA Unknown 100gs = 400gs 2 = 100Hz N/A N/A N/A N/A QuC Output copocitor 40µC 5,3mA/cm²	Unknown 330g 102x152x51 Plastics Biphose asymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown Vinknown N/A N/A N/A 0µC Output capactor 60µC 20,4mA/cm²	Unknown Unknown Unknown Unknown Plastos Biphase symmethical Rectargular Unknown Unknown Unknown Unknown Unknown Unknown NA NA N/A N/A OpC Same positive and negative impulse Unknown	420g 148:80x30 Abuntneum Biphasic symmetricol Rectorgular, Tromqular 50V 200V N/A d1 100mA 100mA 100mA N/A 15µs 999µs 1 - 200Ht N/A N/A N/A N/A OµC Some positive and negative impulse d0µC b,0mA/cm²
Compliance with 21 CFR 898? Weight Weight Dimensions (WishbD) in [mm] Housing Motiand and Constr. Output Specifications Woreldorm Shape Masmum Output Votage (5000) Masmum Output Votage (10\text{S0}) Masmum Output Votage (10\text{S0}) Masmum Output Votage (10\text{S0}) Masmum Output Votage (10\text{S0}) Masmum Output Current (5000) Masmum Output Current (2\text{S0}) Pulse Width (specify units) Frequency [Ht] For interferential modes only: Beal Frequency [Ht] For multiphosis waveforms only: Symmetrical phoses? For multiphosis waveforms only: Symmetrical phoses? For multiphosis waveforms only: Ehase Duration (including units): Net Charge [uC] Masmum Current Density [mA/cm] (5000) Masmum Power Density [mA/cm] (5000) Musmum Power Density [Widm] (50000) Musmum Power Density [Widm] (50000) Burst Mode (e.e., pulse trans): Pulses per burst Burst Mode (e.e., pulse trans):	Yes A40g 175r95s30 Plostica Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 50µs - 400µs i - 1400tz N/A N/A N/A N/A N/A OµC Some positive and negative impulse 40µC 12,5mA/cm² 7,9mW/cm²	Unknown 158g 114x80x31 Plostoc Bephosic asymmetrical Rectangular with discharge 55V 164V Unknown 100mA B2mA Unknown 100µs = 400µs 2 = 100Hz N/A N/A N/A N/A N/A QC Output capacitor 40µC 5,3mA/cm² 1,7mW/cm²	Unknown 330g 102x152x51 Plastics Biphosic asymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown 50gs - 400gs 2 - 100Hz N/A N/A N/A N/A QuC Output capactor 60gC 20,4mA/cm² 6,5mW/cm²	Unknown Unknown Unknown Unknown Plastos Biphase symmethical Rectangular Unknown Unknown Unknown Unknown Unknown Noknown Unknown	420g 148190x30 Abuntnum Abuntnum Biphasic symmetrical Rectangular, Transquiar 50V 200V N/A
Compliance with 21 CFR 898? Weight Weight Dimensions (WathD) in [mm] Housing Motianal and Constr. Output Specifications Worelorin Shape Mazmum Output Votage (5000) Mazmum Output Votage (10\text{Shape} Mazmum Output Votage (10\text{Shape} Mazmum Output Votage (10\text{Shape} Mazmum Output Votage (10\text{Shape} Mazmum Output Current (5000) Mazmum Output Current (10\text{Shape} Mazmum Output Current (10\text{Shape} Mazmum Output Current (10\text{Shape} Frequency [htt] For interferential modes only: Beal Frequency [htt] For multiphose waveforms only: Phase Pourton (including units): Net Charge [uC per pulse]: (5000) Mazmum Power Density Putses per burst Burst Mode (s.e. pulse trans): Putses per second Suss Mode (s.e. pulse trans): Putses per second	Yes A40g 175x95x30 Plostica Biphosic symmetrical Rectargular 50V 115V N/A 100mA 58mA N/A 50µs - 400µs 1 - 140Hz N/A N/A N/A N/A OµC Some positive and negative impulse 40µC 12,5ma/cm² 7,9mW/cm²	Unknown 158g 114x80x31 Plostos 8-phosic asymmetrical Rectangular with discharge 55V 164V Unknown 100mA 82mA Unknown 100µs = 400µs 2 = 100Hz N/A N/A N/A N/A OµC Output capoortor 40µC 5.3mA/cm² 1,7mW/cm²	Unknown 330g 102x152x51 Plastics Biphosic asymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown Vnknown Unknown 50µs = 400µs 2 = 100Hz N/A N/A N/A N/A OµC Output capactor 60µC 20,4mA/cm² 6,5mW/cm²	Unknown Unknown Unknown Unknown Plastos Biphase symmethical Rectangular Unknown Unknown Unknown Unknown Unknown N/A	420g 148x90x30 Abminism Biphasic symmetrical Rectangular, Trongular 50V 200V N/A G1 100mA 100mA 100mA 15ps - 999 ps 1 - 200Hz N/A N/A N/A Opt Some positive and negative impulse 80 pC 5,0mA/cm² 30,9mW//cm² N/A
Compliance with 21 CFR 898? Weight Weight Dimensions (WartbD) in [mm] Housing Motional and Constr. Output Specifications Wordorm Shope Mosmum Output Votage (5000) Mosmum Output Votage (10\s0) Mosmum Output Votage (10\s0) Mosmum Output Votage (10\s0) Mosmum Output Current (300) Mosmum Output Current (300) Mosmum Output Current (300) Frequency (11) For interferential modes only: Beal Frequency (11) For interferential modes only: Beal Frequency (11) For multiphose waveforms only: Phase Duration (including units): Net Charge (units) Mosmum Phase (units) Mosmum	Yes A40g 175r95r30 Plostics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 50µs - 400µs 1 - 140hz N/A N/A N/A N/A 0µC Some positive and negative impulse, 40µC 12.5m4/cm² 7,9mW/cm² N/A N/A N/A N/A N/A	Unknown 158g 114x80x31 Plastes Biphosic caymentrical Rectangular with discharge 55V 164V Unknown 100mA B2mA Unknown 100pts = 400pts 2 = 100pts N/A N/A N/A OptC Output capacitor 40pC 5,3mA/cm² 1,7mW/cm² N/A N/A N/A	Unknown 330g 102x152x51 Plastes Biphose asymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown 50gs - 400gs 2 - 100Hz N/A N/A N/A N/A Output capactor 60g/C 20,4mA/cm² 6,5mW/cm² N/A N/A N/A	Unknown Unknown Unknown Unknown Plastos Biphase symmethical Rectangular Unknown Unknown Unknown Unknown Unknown N/A	420g 14880300 Abummum Biphasic symmetrical Rectangular, Tranquilar 50V 700V N/A G1 100mA 100mA 100mA 15pia - 999pia 1 - 200Ht N/A N/A N/A OpiC Some positive and negative impulse 80pC 5,0mA/cm² 39,9mW/cm² N/A N/A N/A N/A
Compliance with 21 CFR 888? Weight Dimensions (WaftbD) in [mm] Housing Moland and Constr. Output Specifications Worwlorm Shape (5000) Mazimum Output Votage (5000) Mazimum Output Votage (10kg) Mazimum Output Votage (10kg) Mazimum Output Votage (10kg) Mazimum Output Current (6000) Mazimum Output Current (10kg) Pulse Width (specify units) Frequency (Ht] For interferential modes only: Beat Frequency (Ht] For multiphose waveforms only: Phase Duration (including units): Net Charge (µC) Mazimum Phase Charge (µC) (5000) Mazimum Phase Charge (Yes 440g 175:95:30 Postics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 58mA N/A 50µ4 - 400µ6 1 - 140Hz N/A N/A N/A N/A 0µC Some positive and negative impulse 40µC 12,5mA/cm² 7,9mW/cm² N/A	Unknown 158g 114s80x31 Plastos Plastos 8-phoase asymmetrical Rectongular with discharge 50V 164V Unknown 100mA 82mA Unknown 100mA N/A N/A N/A N/A N/A N/A N/A N	Unknown 330g 102x 192x51 Plastics Biphose asymmetrical Rectangular with discharge 50V Unknown 100mA Unknown Unknown 100mA Vinknown Vinknown 000mA Vinknown 0000mA Vinknown 000mA Vinknown	Unknown Unknown Unknown Unknown Plastos Biphase symmethool Rectangular Unknown N/A	420g 148x80x30 Abminum Biphasic symmetricol Rectorgular, Trionigular 50V 200V N/A d1 100mA 100mA 100mA 15pia - 999pia 1 - 200Hz N/A N/A N/A N/A OptC Some positive and negative impulse 80pC 5,0mA/cm² 39,9mW/cm² N/A
Compliance with 21 CFR 868? Weight Dimensions (WishbD) in [mm] Housing Motianal and Constr. Output Specifications Worelarm Shape Mazimum Output Votage (15002) Mazimum Output Votage (15002) Mazimum Output Votage (10102) Mazimum Output Votage (10102) Mazimum Output Current (2010) For multiphosic waveforms only: Symmetrical phoses? For multiphosic waveforms only: Symmetrical phoses	Yes A40g 175r95s30 Plostics Biphosic symmetrical Rectangular 50V 115V N/A 100mA 59mA N/A 100mA 59mA N/A N/A N/A N/A N/A N/A N/A N/A N/A N/	Unknown 158g 114x80x31 Plostoc Biphosic caymentricol Rectongulor with dischorge 50V 164V Unknown 100mA B2mA Unknown 100jus = 400jus 2 = 100jus N/A N/A N/A N/A OµC Output capacitor 40µC 5.3mA/cm² 1,7mW/cm² N/A	Unknown 330g 102x152x51 Plastes Biphose asymmetrical Rectangular with discharge 50V Unknown Unknown 100mA Unknown Unknown 100mA Vinknown Unknown 50gs - 400gs 2 - 100Hz N/A N/A N/A N/A 0µC Output capactor 60µC 20,4mA/cm² 6,5mW/cm² N/A	Unknown Unknown Unknown Unknown Plastos Biphase symmethool Rectorgular Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown N/A N/A N/A N/A N/A N/A N/A N/	420g 148.80s30 Abminium Biphasic symmetricol Rectorgular, Trongular 50V 200V N/A G1 100mA 100mA 100mA 15pis - 999jis 1 - 200Hz N/A N/A N/A OptC Some positive and negative impulse 80piC b,0mA/cm² N/A



Functional Electrical Stimulation Programs:

Characteristics/ Specifications	New Device	Predicate	New Device	Predicate Device	New Device	Predicate Device	New Device	Predicote Device
Basic Unit		Device		Divice		Device		Device
Chrocteristics Program	FES 1 Grasp/Release	Exercise Open	FES 2 Grasp/Release (EMG)	Exercise Open	FES 3 Open/Close	Exercise	FES 4 Open/Close (EMG)	Palmar Grasp
510(k) Number	K080950	K031900	K080950	K031900	K080950	K031900	K080950	K031900
Manufacturer Device Name	Otto Bock STIWELL med4	Ness Handmaster	Otto Bock STIWELL med4	Ness Handmaster	Otto Bock STIWELL med4	Ness Handmaster	Otto Bock STIWELL med4	Ness Handmaster
	Battery Pack Li-	Bottery Pock No	Battery Pack Li-	Battery Pack Ni	Bottery Pock Li-	Bottery Pock Ni	Battery Pock Le	Battery Pack Ni
Power Source(s)	lon 11,1V	Cd 9,6V	lon 11,1V	Cd 9,8V	lon 11,1V	Cd 9,6V	lon 11,1V	Cd 9,6V
Method of Line	Medical Class #	N/A	Medical Class II Power Adapter	N/A	Medical Class II	N/A	Medical Class II	N/A
Current Isolation Leakage Current (normal condition)	Power Adapter N/A (Bottery)	N/A	N/A (Bottery)	N/A	Power Adopter N/A (Battery)	N/A	Power Adopter N/A (Bottery)	N/A
Leokage Current (single laut cond.)	N/A (Battery)	N/A	N/A (Battery)	N/A	N/A (Battery)	N/A	N/A (Battery)	N/A
No. Output Mod.	1	1	1	1	1	1	1	1
No. Output Chan.	3	2	3	2	3 Finger/thumb	5 Finger extensors	3 Finger/thumb	5 Finger extensors
Stimulated Musal.	Wnst extensors Finger flexors Thumb flexor	Finger extensors Thumb extensor	Wrist extensors Finger Revors Thumb flexor	Finger extensors Thumb extensor	extensors Finger flexors Thumb flexor	Thumb extensor Finger flexors Thumb flexor Thenor muscle	extensors Finger flexors Thumb flexor	Thumb extensor Finger flexors Thumb flexor Thenor muscle
No. of EMG Chan.	0	0	1	0	0	0	1	. 0
EMG sensitivity	N/A	N/A	1μV	N/A	N/A	N/A	1µV	N/A
EMG Sampl. Rate	N/A N/A	N/A N/A	3kHz Bipolar	N/A N/A	N/A N/A	N/A N/A	3kHz Bipolar	N/A N/A
EMG detection EMG range (µV)	N/A	N/A	1-2000μV	N/A	N/A	N/A	1-2000μV	N/A
EMG bondwidth	N/A	N/A	70-480Hz	N/A	N/A	N/A	70-480Hz	N/A
EMG signal proc.	N/A	N/A	AVR	N/A	N/A	N/A	AVR	N/A
Synchr, or Allern.?	Alternating	Alternating	Alternating	Alternating	Alternating	Alternating	Alternating	Alternating
Meth. Chan. isol.	Transformer, Inductive couplers	Transformer, Opt isolator	Transformer, Inductive couplers	Transformer, Opt	Transformer, Inductive couplers	Transformer, Opt isolator	Transformer, Inductive couplers	Transformer, Opt isolator
RC or RV?	Regulated Current	Regulated Voltage	Regulated Current	Regulated Voltage	Regulated Current	Regulated Voltage	Regulated Current	Regulated Voltage
Firmwore/?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
PC Software?	No	No	No	Na	No	No	No	No
Aut. Overload Trip	Yes	Unknown	Yes	Unknown	Yer	Unknown	Yes	Unknown
Aut. No-Lood Trip	Yes	Unknown	Yes Yes (10min)	Unknown	Yes	Unknown	Yes	Unknown
Aut. Shut Off Override Control?	Yes (10min) Yes (Stop Button)	No Yes	Yes (Stop Button)	No Yes	Yes (10min) Yes (Stop Button)	No Yes	Yes (10min) Yes (Stop Button)	No Yes
Deploy: On/Off?	Yes (Stop Building	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Display: Low Batt?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Display: V/C Level	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Timer Ronge	15-80mm	Max. 90min	15-60mm	Max. 90min	15-60mm	Mox. 90min	15-80min	Max. 45min
Compliance with Voluntary Standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Unknown	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Unknown	IEC 80601-1 IEC 80601-1-2 IEC 80601-2-10	Unknown	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Unknown
Compliance with 21 CFR 898?	Yes	Unknown	Yes	Unknown	Yes	Unkaown	Yes	Unknown
Weight	440g	685g	440g	685g	440g	685g	440g	685g
Dimensions	175:95:30	172x91x40	175x95x30	172x91x40	175x95x30	172x91x40	175x95x30	172x91x40
(WxHsD) in (mm) Housing Material		(Control unit)		(Control unit)		(Control unit)		(Control unit)
ond Construction Output	Plastics	Plostics	Plostics	Plastice	Postics	Ploatica	Plastics	Plastics
Specifications	Biphasic	Biphasic	Biphasic	Biphosic	Biphosic	Biphosic	Biphasic	Biphasic
Waveform	aymmetrica)	symmetrica!	symmetrica!	symmetrical	symmetrical	symmetrical	symmetrical	symmetrical
Shope	Rectangular	Sinusoidal	Rectangular	Sinusoidal	Rectangular	Sinusoidal	Rectongular	Sinusoidal
Maximum Oulput Voltage (500Ω)	50V	106V	50V	106V	50V	106V	50V	1067
Maximum Output Voltage (2kΩ) Maximum Output	115V	163V	115V	163V	115V	163V	115V	163V
Voltage (10kΩ) Maximum Output	N/A	Unknown	N/A	Unknown	N/A	Unknown	N/A	Unknown
Current (500Ω)	100mA	212mA	100mA	212mA	100mA	212mA	100mA	212mA
Maximum Output Current (2kΩ)	58mA	92mA	58mA	92mA	58mA	92mA	58m A	92mA
Maximum Output Current (10kΩ) Pulse Width	N/A 50-400µa	Unknown 100-350µs	N/A 50-400µs	Unknown 100-350µs	N/A 50-400μ s	Unkлаwn 100-350µs	N/A 50-400μs	Unknown 100-500µs
	1-140Hz	38Hz	1-140Hz	36Hz .	1=140Hz	36Hz	1-140Hz	18Hz
Frequency [Hz]	Delquit: 35Hz 0μC	оµС	Default: 35Hz 0μC	0μC	Default: 35Hz 0µC	ОрС	Default: 35Hz 0μC	0μC
per pulse]; (500Ω) Maximum Phase Charge IuCl	- 40μC	75µC	40μ C	75µC	40µC	75µC	40μC	106μC
Chorge [μC] (500Ω) Moximum Current		·	·				· · · · · · · · · · · · · · · · · · ·	
Density (mA/cm²) (500Ω) Maximum Power	12,5 mA/cm ²	15,9mA/cm²	12,5mA/cm²	15,9mA/cm²	12,5mA/cm²	15,9mA/cm ²	12,5mA/cm²	15,9mA/cm²
Maximum Power Density [W/cm²] (500Ω) Burst Mode:	7,9mW/cm ²	0,39 mW/cm ²	7,9mVV/cm²	0,39 mW/cm ³	7,9mW/cm²	0,39 mVV/cm ²	7,9mW/cm²	0.39 mW/cm ²
Pulses per burst Burst Mode:	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Bursts Mode: Burst	N/A	N/A N/A	N/A N/A	N/A N/A	N/A N/A	N/A N/A	N/A N/A	N/A N/A
duration (seconds) Burst Mode: Duty	N/A N/A	N/A	N/A N/A	N/A N/A	N/A N/A	N/A	N/A N/A	N/A N/A
Cycle ON Time [sec.]	1 – 20s	Unknown	1 – 20s	Unknown	1 – 20s	Unknown	1 - 20s	Trigger controlled
OFF Time (sec.)	1 ~ 30s	Unknown	Trigger controlled (min. 1 – 30s)	Unknown	1 - 30s	Unknown	Trigger cartrolled (min. 1 - 30s)	Trigger controlled
O. 1 141-5 (000.)								



Incontinence Programs:

Characteristics/	New Device	Predicate	New Device	Predicate	New Device	Predicate	New Device	Predicate
Specifications	New Delike	Device	NOW DETRO	Device	1107 50120	Device	- Italia Derica	Device
Basic Unit Chrocteristics								
Program	Ül	P2, P3	U2	P1	U3	P4	U4	EMG Script
510(k) Number	Urge K080950	Urge K032988	\$tress K080950	Stress K032988	Mixed K080950	Mixed K032988	Feedback K080950	K053434
		1		1			Otto Bock	Thought
Monufacturer	Otto Bock	Donmeter A/S	Otto Bock	Donmeter A/S	Otto Bock	Donmeter A/S		Technology Ltd.
Device Name	STIWELL med4 Bottery Pock Li-	Elpho 4 Conti Battery NMH or	STIWELL med4 Bottery Pock Li-	Elpha 4 Conti Battery NMH or	STIWELL med4 Battery Pock Li-	Elpha 4 Contr Bottery NMH or	STIWELL med4 Battery Pack Ly	Myotroc Infinity Battery Pack
Power Source(s)	lon 11,1V	Alkoline 9V	lon 11,1V	Alkoline 9V	lon 11,1V	Alkoline 9V	lon 11.1V	NMH
Method of Line	Medicol Class P	N/A	Medical Class II	N/A	Medical Class II	N/A	Medical Class II	Medicai Class II
Current isolation Leakage Current	Power Adapter		Power Adapter	!	Power Adopter		Power Adopter	Power Adopter
(normal condition)	N/A (Battery)	N/A (Bottery)	N/A (Battery)	N/A (Battery)	N/A (Battery)	N/A (Bottery)	N/A (Battery)	N/A (Bottery)
Leakage Current	N/A (Battery)	N/A (Battery)	N/A (Battery)	N/A (Bottery)	N/A (Bottery)	N/A (Bottery)	N/A (Battery)	N/A (Battery)
(single fault cond.) No. Output Mod.	1	1	1	1	1	h	0	
No. Output Chan.	1	11	1	1	†	1	0	0
No. of EMG Chan.	0	0	0	0	0 N/A	0 N/A	1	1
EMG sensitivity EMG Sampl. Rate	N/A N/A	N/A N/A	N/A N/A	N/A N/A	N/A	N/A	1 juV 3kHz	<0,1µV 2,048kHz
EMG detection	N/A	N/A	N/A	N/A	N/A	N/A	Bipolar	Bipolar
EMG ronge (µV)	N/A	N/A	N/A	N/A	N/A	N/A	1-2000μV	0-2000μ∀
EMG bandwiath EMG signal proo.	N/A ·	N/A N/A	N/A N/A	N/A N/A	N/A N/A	N/A N/A	70-480Hz AVR	10Hz-1kHz RMS
Synchr. or Altern.?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Meth. Chan. Isol.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RC or RV?	Regulated Current	Regulated Current	Regulated Current	Regulated Current	Regulated Current	Regulated Current	N/A	N/A
Firmwore/? Aut. Overload Trip	Yes Yes	Yes Yes	Yes Yes	Yes Yes	Yes Yes	Yes Yes	Yes N/A	Yes N/A
Aut. No-Load Trip	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A
Aut, Shut Off	Yes (10mm)	ZeY	Yes (10mm)	Yes	Yea (10min)	Yea	Yes (10min)	Unknown
Overnde Control? Disploy: On/Otl?	Yes (Stop Button) Yes	Yes Yes	Yes (Stop Button) Yes	Yes Yes	Yes (Stop Button) Yes	Yes Yes	Yes (Stop Button) Yes	Yes Yes
Diaplay: Low Batt?	Yes	Yes	Yes	Yea	Yes	Yes	Yes	Yes
Timer Ronge	5 – 25min	5 - 95min	5 – 25mn	5 – 95min	5 - 25min	5 - 95min	2-4min	1-120min
Compliance with Voluntary	#EC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60801-1 (EC 60801-1-2	IEC 80601-1 IEC 60601-1-2	IEC 80601-1 IEC 80601-1-2	IEC 80601-1 IEC 60601-1-2	Unknown
Standards?	IEC 60601-2-10	IEC 60801-2-10	IEC 60601-2-10	IEC 60801-2-10	IEC 60601-2-10	IEC 80601-2-10	IEC 60601-2-10	O.A.IOMI
Compliance with	Yes	Unknown	Yes	Unknown	Yea	Unknown	Yes	Unknown
21 CFR 898? Weight	440g	158g	440g	158g	440g	158g	440g	330g
Dimensions		-	175x95x30	114x60x31	175x95x30	114x60x31	175x95x30	102x152x51
[MxHxD] in [mm]	175x95x30	114z60z31	(1719317)0	114100131	173193130	114100131	(10180100	1023132331
Housing Material and Construction	Plantics	Plastics	Plostics	Plastics	Plostics	Plostics	Plastics	Plostics
Output								
Specifications	Biphasic	Pulsed biphasic	Biphasic	Pulsed biphosic	Behose	Pulsed biphosic		
Waveform	symmetrical	asymmetrical	symmetrical	osymmetrical	symmetricol	osymmetrical	N/A	N/A
Shape	Rectangular	Rectangular with	Rectangular	Rectangular with	Rectangular	Rectongular with	N/A	N/A
Maximum Output		dischorge		discharge		discharge		
Voltage (500Ω)	50V	50V	50V	50V	50V	50V	N/A	N/A
Maximum Output	115V	150V	115V	150V	115V	1500	N/A	N/A
Voltage (2kΩ) Maximum Output		·						
Voltage (10kΩ)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Maximum Output	100mA	100mA	100mA	100mA	100mA	100mA	N/A	N/A
Current (500Ω) Maximum Output			50-±	90-4	ED - *	80-1	Mra	3173
Current (2kΩ)	58mA	80mA	58mA	80mA	58mA	80mA	N/A	N/A
Maximum Output Current (10kΩ)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pulse Width	500µs	50-400µs	300µs	50-400µs	350-500µs	50-400µa	N/A	N/A
	10Hz	1-10Hz	35Hz	20-80Hz	5-60Hz	1-80Hz	N/A	N/A
Frequency [Hz]								
Net Charge fuC	ОμС	ομС	θμΟ	0µC	ОμС	ομС	N/A	N/A
Net Charge (μC per pulse); (500Ω) Maximum Phase	ομC	ομα	θμC		0μC		N/A	
Net Charge (μC per pulse); (500Ω) Maximum Phase Charge (μC)				0μC 40μC		ο _μ C 40μC	N/A N/A	N/A
Net Charge (μC per pulse); (500Ω) Maximum Phase Charge (μC) (500Ω)	ομC 50μC	0μC 40μC	онс зонс	40μC	ομC 50μC	40µC		
Net Charge (μC per pulse): (500Ω) Maximum Phase Charge (μC) (500Ω) Surface area of the electrodes	0μC 50μC Axel Goord (Surtace) P8100	0μC 40μC Vaginal: 4,9cm²	θμC 30μC Axel Goord (Surface) PB100	40μC Vagmol: 4,9cm²	0μC 50μC Axel Goord (Surloce) PR100	40μC Vaginal: 4,9cm²		
Net Charge (µC per pulse): (5000) Maximum Phase Charge (µC) (5000) Surface area of the electrodes [cm²]	ομC 50μC Axel Goard	σμC 40μC Vaginal: 4,9cm ² Anal: 3 cm ²	ομC 30μC Axel Gaard	40μC Vaginal: 4,9cm ² Anal: 3 cm ²	ομC 50μC Axel Gaard	40µC Vaginal: 4,9cm² Anal: 3 cm²	N/A	N/A
Net Charge (μC per pulse): (500Ω) Maximum Phase Charge (μC) (500Ω) Surface area of the electrodes	0μC 50μC Axel Goord (Surtace) P8100	σμC 40μC Voginal: 4,9cm ² Anal: 3 cm ² Vaginat: 20,4mA/cm ²	θμC 30μC Axel Goord (Surface) PB100	40µC Vaginal: 4,9cm² Anal: 3 cm² Vaginal: 20,4m4/cm²	0μC 50μC Axel Goord (Surloce) PR100	40µC Vaginal: 4,9cm² Anal: 3 cm² Vaginal: 20,4m4/cm²	N/A	N/A
Net Chorge (µC) per pulse); (800Ω) Maximum Phase Chorge (µC) (600Ω) Surface area of the electrodes [cm²] Maximum Current Density [mA/cm²] (600Ω)	θμC 50μC Axel Goord (Surface) PR100 21,2cm ²	OμC 40μC Vaginal: 4,9cm ² Anal: 3 cm ² Vaginat: 20,4mA/cm ² Anal: 33,3mA/cm ³	θμC 30μC Axel Goord (Surface) PR100 21,2cm ²	40µC Vaginat: 4,9cm² Anal: 3 cm² Vaginat: 20,4mA/cm² Anal: 33,3mA/cm²	θμC 50μC Axal Goord (Surloce) PR100 21,2cm ²	40µC Vaginal: 4,9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm²	N/A N/A	N/A N/A
Net Charge (µC) per pulse]: (300Ω) Maximum Phase Charge (µC) (500Ω) Surface area of the electrodes [cm²] Maximum Current Density [mA/cm²] (500Ω) Maximum Power	0μC 50μC Axel Goord (Surtace) PR100 21,2cm ² 4,7 mA/cm ²	OμC 40μC Voginol: 4,9cm ² Anol: 3 cm ² Vaginat: 20,4mA/cm ² Anol: 33,3mA/cm ³	δμC 30μC Axel Goord (Surface) PR100 21,2cm ² 4,7 mA/cm ²	40µC Vaginat: 4,9cm² Anal: 3 cm² Vaginat: 20,4mA/cm² Anal: 33,3mA/cm² Vaginat: 2,3mW/cm²	ομC 50μC Axel Goord (Surloce) PR100 21,2cm ² 4,7 mA/cm ²	40µC Vaginal: 4,9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,9mA/cm²	N/A N/A	N/A N/A N/A
Net Chorge (µC per pulse): (BOOC) Maximum Phase Chorge (µC) (6005) Surface area of the electrodes [cm²] Maximum Current Density [mA/cm²] (8000) Maximum Power Density [W/cm²] (5000)	θμC 50μC Axel Goord (Surface) PR100 21,2cm ²	OμC 40μC Vaginal: 4,9cm ² Anal: 3 cm ² Vaginat: 20,4mA/cm ² Anal: 33,3mA/cm ³	θμC 30μC Axel Goord (Surface) PR100 21,2cm ²	40µC Vaginat: 4,9cm² Anal: 3 cm² Vaginat: 20,4mA/cm² Anal: 30,3mA/cm²	θμC 50μC Axal Goord (Surloce) PR100 21,2cm ²	40µC Vaginal: 4,9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm²	N/A N/A	N/A N/A
Net Chorge (µC por pulse): (800C) Maximum Phase Chorge (µC): (600C) Surface area of the electrodes [cm²] Maximum Current Density [mA/cm²]: (800C) Maximum Power Density [W/cm²]: (800C) Bursty [W/cm²]: (800C) Bursty [W/cm²]: (800C) Bursty [W/cm²]: (800C)	ΟμC 50μC Axel Goord (Surface) PR100 21,2cm ² 4,7 mA/cm ² 23,5 μW/cm ²	OμC 40μC Voginol: 4,9em² Anol: 3 cm² Vaginot: 20,4mA/cm² Anol: 33,mA/cm² Vaginot: 2,3mW/cm² Anol: 33,9mW/cm²	ΟμC 30μC Axel Goord (Surface) PR100 21,2cm ² 4.7 mA/cm ²	40µC Vaginat: 4,9cm² Anal: 3 cm² Vaginat: 20,4mA/cm² Anal: 33,3mA/cm² Vaginat: 2,3mW/cm²	OμC 50μC Asa' Gaard (Surface) PR100 21,2cm² 4.7 mA/cm²	40µC Vaginal: 4,9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm² Vaginal: 2,3mW/cm²	N/A N/A N/A	N/A N/A N/A
Net Chorge (μC pur pulse): (800C) Maximum Phose Chorge (μC) (800Ω) Surface area of the electrodes [cm²] Maximum Current Density (mA/cm²] (800Ω) Maximum Power Density (W/cm²) (800Ω) Bursa Mode: Pulses per burst	ΟμC 50μC Axel Goord (Surface) PR100 21,2cm ² 4,7 mA/cm ² 23,5 μW/cm ²	OμC 40μC Voginol: 4,9cm² And: 3 cm² Vagnat: 20,4mA/cm² 20,4mA/cm² Vagnat: 2,3mW/cm² And: 33,9mW/cm² N/A	OμC 3OμC Axel Goard (Surface) PR100 21,2cm² 4.7 mA/cm² 105 μW/cm²	Vognot 4.9cm ² Anol: 3 om ² Vognot: 20,4mA/cm ² Anol: 33,0mA/cm ² Vognot: 2,3mW/cm ² Anol: 33,8mW/cm ² N/A	OµC 50µC Axel Goard (Surloce) PR100 21,2cm² 4.7 mA/cm² 0,42 mW/cm²	40µC Vaginat 4,9cm² Anol: 3 cm² Vaginat: 20,4mA/cm² Anol: 33,mA/cm² Vaginat: 2,3mW/cm² Anol: 3,9mW/cm² N/A	N/A N/A N/A N/A	N/A N/A N/A N/A
Net Chorge (μC pur pulse): (BOOΩ) Maximum Phose Chorge (μC) (500Ω) Surface area of the electrodes (cm²) Maximum Current Density (mA/cm²) (500Ω) Maximum Current Density (mA/cm²) (500Ω) Maximum Power Density (W/cm²) (500Ω) Burst Mode: Burst Mode: Bursts per second	ΟμC 50μC Axel Goord (Surface) PR100 21,2cm ² 4,7 mA/cm ² 23,5 μW/cm ²	OμC 40μC Voginol: 4,9em² Anol: 3 cm² Vaginot: 20,4mA/cm² Anol: 33,mA/cm² Vaginot: 2,3mW/cm² Anol: 33,9mW/cm²	ΟμC 30μC Axel Goord (Surface) PR100 21,2cm ² 4.7 mA/cm ²	Vaginat: 4,9cm ² Anal: 3 om ² Vaginat: 20,4mA/cm ² Anat: 33,3mA/cm ² Vaginat: 2,3mW/cm ² Anat: 3,8mW/cm ²	OμC 50μC Asa' Gaard (Surface) PR100 21,2cm² 4.7 mA/cm²	40μC Vaginal: 4,9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm² Vaginal: 2,3mW/cm² Anal: 3,8mW/cm² Anal: 3,8mW/cm²	N/A N/A N/A	N/A N/A N/A
Net Chorge (µC per pulse): (BOOG) Maximum Phase Chorge (µC) Maximum Phase Chorge (µC) (BOOR) Surface area of the electrodes [cm²] Maximum Current Density [MA/cm²] (BOOG) Maximum Power Density [W/cm²] (BOOG) Burst Mode: Burst Mode: Burst per second Burst Mode: Mode	ΟμC 50μC Axel Goord (Surface) PR100 21,2cm ² 4,7 mA/cm ² 23,5 μW/cm ²	OμC 40μC Voginol: 4,9cm² And: 3 cm² Vagnat: 20,4mA/cm² 20,4mA/cm² Vagnat: 2,3mW/cm² And: 33,9mW/cm² N/A	OμC 3OμC Axel Goard (Surface) PR100 21,2cm² 4.7 mA/cm² 105 μW/cm²	Vognot 4.9cm ² Anol: 3 om ² Vognot: 20,4mA/cm ² Anol: 33,0mA/cm ² Vognot: 2,3mW/cm ² Anol: 33,8mW/cm ² N/A	OµC 50µC Axel Goard (Surloce) PR100 21,2cm² 4.7 mA/cm² 0,42 mW/cm²	40µC Vaginat 4,9cm² Anol: 3 cm² Vaginat: 20,4mA/cm² Anol: 33,mA/cm² Vaginat: 2,3mW/cm² Anol: 3,9mW/cm² N/A	N/A N/A N/A N/A	N/A N/A N/A N/A
Net Chorge (μC per pulse): (BOOΩ) Maximum Phose Chorge (μC) (500Ω) Surface area of the electrodes [cm²] Maximum Current Density (mA/cm²] (500Ω) Maximum Power Density (mA/cm²] (500Ω) Maximum Power Density (MA/cm²] (500Ω) Maximum Power Density (MA/cm²) (500Ω) Maximum Phose Chorac (MA/cm²) (500Ω) Maximum Current Density (MA/cm²) (500Ω) Maximum Current Density (MA/cm²) (500Ω) Maximum Current Density (MA/cm²) (500Ω) Maximum Phose Chorac (MA/cm²)	OμC 50μC Axel Goord (Surtace) PR100 21,2cm² 4,7 mA/cm² 23,5 μW/cm² N/A N/A N/A	OµC 40µC Voginol: 4,9cm² Anol: 3 cm² Vaginal: 20,4mA/cm² Anol: 33,4mA/cm² Vaginal: 2,3mW/cm² Anol: 3,8mW/cm² N/A N/A N/A	ΟμC 30μC Arel Gaard (Surface) PR100 21,2cm² 4.7 mA/cm² 105 μW/cm² N/A N/A N/A	40μC Vaginal: 4.9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm² 2,3mW/cm² 2,3mW/cm² Anal: 3,8mW/cm² N/A N/A	OµC 50µC As al Gacrd (Surface) PR100 21,2cm² 4.7 mA/cm² 0,42 mW/cm² N/A N/A	40μC Vaginal: 4.9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm² Vaginal: 2,3mW/cm² Anal: 3,8mW/cm² N/A N/A N/A	N/A N/A N/A N/A N/A N/A N/A	N/A N/A N/A N/A N/A N/A N/A N/A
Net Chorge (µC per pulse): (BOOQ) Maximum Phose Chorge (µC) (50002) Maximum Phose Chorge (µC) (50003) Maximum Current Density (mA/cm²) (50002) Maximum Power (50002) Maximum Power (50002) Maximum Power Surst Mode: Pulses per burat Burst Mode: Burst Mode: Burst Mode: Burst pose second Burst Mode: Cycle	ΟμC 50μC Axel Goord (Surtace) PR100 21,2cm² 4,7 mA/cm² 23,5 μW/cm² N/A N/A N/A N/A	OμC 40μC Voginol: 4,9cm² And: 3 cm² Vaginat: 20,4mA/cm² 20,4mA/cm² 2,3mW/cm² And: 33,9mW/cm² And: 3,8mW/cm² N/A N/A N/A	OμC 3OμC Axel Goord (Surface) PR100 21,2cm² 4.7 mA/cm² 105 μW/cm² N/A N/A N/A N/A	Vognot 4.9cm² Anal: 3 om² Vognot: 3 om² Vognot: 20,4mA/cm² Anal: 3 3mA/cm² Vognot: 2,3mW/cm² Anal: 3,8mW/cm² N/A N/A N/A	ΟμC 50μC Axel Goard (Surloce) PR100 21,2cm² 4.7 mA/cm² 0,42 mW/cm² N/A N/A N/A N/A	40µC Vaginat 4,9cm² Anol: 3 cm² Vaginat: 20,4mA/cm² Anol: 3,9mA/cm² Vaginat: 2,3mW/cm² Anol: 3,9mW/cm² N/A N/A N/A	N/A N/A N/A N/A N/A N/A N/A N/A	N/A
Net Chorge (µC per pulse): (BOOG) Maximum Phose Chorge (µC) (600G) Maximum Phose Chorge (µC) (600G) Surface area of the electrodes [cm²] Density [mA/cm²] (800G) Maximum Current Density [mA/cm²] (800G) Maximum Power Density [W/cm²] (600G) Burst Mode: Burst Mode: Burst Mode: Burst duration (second)	OμC 50μC Axel Goord (Surtace) PR100 21,2cm² 4,7 mA/cm² 23,5 μW/cm² N/A N/A N/A	OµC 40µC Voginol: 4,9cm² Anol: 3 cm² Vaginal: 20,4mA/cm² Anol: 33,4mA/cm² Vaginal: 2,3mW/cm² Anol: 3,8mW/cm² N/A N/A N/A	ΟμC 30μC Arel Gaard (Surface) PR100 21,2cm² 4.7 mA/cm² 105 μW/cm² N/A N/A N/A	40μC Vaginal: 4.9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm² 2,3mW/cm² 2,3mW/cm² Anal: 3,8mW/cm² N/A N/A	OµC 50µC As al Gacrd (Surface) PR100 21,2cm² 4.7 mA/cm² 0,42 mW/cm² N/A N/A	40μC Vaginal: 4.9cm² Anal: 3 cm² Vaginal: 20,4mA/cm² Anal: 33,3mA/cm² Vaginal: 2,3mW/cm² Anal: 3,8mW/cm² N/A N/A N/A	N/A N/A N/A N/A N/A N/A N/A	N/A N/A N/A N/A N/A N/A N/A N/A



TENS:

Characteristics/ Specifications	New Device	Predicate Device	Predicate Device	Predicate Device
Basic Unit Chracteristics				
510(k) Number	K080950	K032954	K032954	K940301
Monufacturer	Otto Bock	Donmeter A/S	Donmeter A/S	Compex SA
Device Name, Madel	STIWELL med4	Elpho II1000	Elpho II3000	STIWELL med4
Power Source(s)	Battery Pack L-lon 11,1V	Bottery NiMH or Alkoline 9V	Battery Pack NMH or Alkaline 9V	Bottery Pock Li-lon 11,1V
Method of Line Current Isolation	Medical Class II Power Adopter – Mascot	N/A	N/A	Medical Class II Power Adapter - Mascol
Patient Leakage Current (normal	(12,6VDC-15,1W) N/A (Battery)	N/A (Battery)	N/A (Battery)	(12.6VDC-15,1W) N/A (Battery)
condition) Patient Leakage Current (single fault	 - 		N/A (Battery)	N/A (Battery)
condition) Number of Output Modes	N/A (Bottery)	N/A (Battery)	WA (Ballery)	14/A (Dullery)
Number of Output Channels	4	2	2	4
Number of EMG (input) Channels	N/A	N/A	N/A	N/A
EMG sensitivity	N/A	N/A	N/A	N/A
EMG Sompling Rate	N/A	N/A	N/A	N/A
EMG detection (bipolar/ monopolar)	N/A	N/A	N/A	N/A
EMG range (µV)	N/A	N/A	N/A	N/A
EMG bandwidth	N/A	N/A	N/A	N/A
EMG signal processing (eg. RMS)	. N/A	N/A	N/A	N/A
Synchronous or Alternating?	Alternating	Unknown	Unknown	Synchronous
Method of Channel Isolation	Transformer, Inductive couplers	Unknown	Unknown	Transformer
Regulated Current or Regulated Voltage?	Regulated Current	Regulated Current	Regulated Current	Regulated Current
Software/Firmware/ Microprocessor	Yes	Yes	Yes	Yes
Control? Automatic Overload Trip?	Yes	Yes	Yes	Yes
Automotic Oversodd Trip?				Yes
Automotic No-Load Trip? Automotic Shut Off?	Yes Yes (10min)	Yes Yes	Yes Yes	Unknown
		Yes	Yes	Yes
Potient Override Control?	Yes (Stop Button)	Yes	Yes	Yes
Indicator Display: On/Off Status?	Yes Yes	Yes	Yes	Yes
Indicator Display: Low Battery?	169	163	165	185
Indicator Display: Votage/Current Level?	Yes	Yes	20Y	Yes
Timer Range [minutes]	10 – 120min	-45min and cont.	5 - 95min and cont.	3 – 54min
Compliance with Voluntary Standards? (if yes, specify)	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Unknown
	IEC 60601-2-10	IEC 80601-2-10	IEC 60801-2-10	
Compliance with 21 CFR 998?	Yes	Unknown	Unknown	Unknown
Weight	440g	168g	158g	420g
Demensiona (WxHxD) in [mm]	175±95±30	117x60x31	114x60x31	148x80x30
Housing Material and Construction Output Specifications	Plostes	Plostics	Plostics	Aluminium
Waveform (e.g., pulsed monophasic, biphosic)	Biphasic symmetrical	Biphasic asymmetrical	Biphosic asymmetrical	Biphasic symmetrical
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular with discharge	Rectangular with discharge	Rectangular
Maxmum Output Voltage (500Ω)	50V	20V	50V	50V
Maximum Output Voltage (2kΩ)	115V	76V	164V	200√
Maximum Output Voltage (10kΩ)	N/A	Unknown	Unknown	N/A
Maximum Output Current (500Ω)	100mA	40mA	B0mA	100mA
Maximum Output Current (2kΩ)	58mA	38mÅ	B2mA	100mA
Maximum Output Current (10kΩ)	N/A	Unknown	Unknown	N/A
Pulse Width (specify units)	150με, 200με	150 με, 160 με, 200 με	50 – 400µx	Unknown
Frequency [Hz]	2 – 100Hz	2 - 120Hz	0,5 – 150Hz	Unknown
For interferential modes only: Beat Frequency (Hz)	N/A	N/A	N/A	N/A
For multiphosic waveforms only:	N/A	N/A	N/A	N/A
Symmetrical phases? For multiphosic waveforms only:				1477
Phase Durotion (including units);	1	l	I .	N/A
state range if applicable;	N/A	N/A	N/A	
both phases, if asymmetrical Net Charge [μC per pulsa]; (500Ω) If zero, state method of achieving zero	0μC	ОрС	оµС	OμC Some positive and regative impulse
both phases, if asymmetrical Net Charge [µC per pulse]; (500Ω) If zero, state method of achieving zero net charge.	θμC Same positive and negative impulse	OμC Output copocitor	ОµС Output copecitor	Some positive and negative impulse
both phases, if asymmetrical Net Charge [µC per pulse]; (500Ω) If zero, state method of achieving zero net charge. Maximum Phase Charge (µC) (500Ω)	0μC	ОрС	оµС	ΟμC Some positive and negative impulse Unknown
both phases, if asymmetrical Net Charge [µC per pulse]; (5000) If zero, state method of achieving zero net charge. Maximum Phase Charge [µC] (5000) Maximum Cutrent Density [mA/cm²] (5000)	θμC Same positive and negative impulse	OμC Output copocitor	ОµС Output copecitor	Some positive and negative impulse
both phases, if asymmetrical Net Charge [µC per pulsa]; (5002) If zero, state method of achieving zero net charge. Maximum Phase Charge [µC] (5000) Maximum Current Density [mA/cm²]	θμC Same positive and negative impulse 20μC	ОµС Output сороско ВµС	0μC Ουτρυί οοροσίοι 24μC	Same positive and negative impulse Unknown
both phases, if asymmetrical Net Charge (Lip Per pulsa); (5000) if zero, state method of ochieving zero net charge. Maemum Phase Charge (µC) (5000) Maemum Current Denesty [mWcm*] (5000) Maemum Power Denesty (Witcm*) (5000) ung emallest electrode	OµC Same positive and negative impulse 20µC 12,5mA/cm²	OµC Output copacifor BµC 2,1 mA/om ⁷	ΟμC Output copector 24μC 3,2mA/cm²	Some positive and negative impulse Unknown 5,0mA/cm²
both phases, if asymmetrical Net Charge (pc per pulsa); (5000) If zero, state method of ochieving zero net charge Maximum Phase Charge (µC) (5000) Maximum Phase Charge (µC) (5000) Maximum Power Density (W/cm²) (5000) using smallest electricale conductive surface area Surface (x-pulse trans); Pulses Surface (x-pulse trans); Pulses	0μC Same positive and regative impulse 20μC 12,5mA/cm² 1,0mW/cm²	ΟμC Ουέρυ! τοροσέαν ΘμC 2,1 mA/cm² 0,09mW//cm²	OµC Output oppositor 24µC 3,2mA/cm² 1,4mW/cm²	Some positive and negative impulse Unknown 5,0mA/cm² Unknown
both phases, if asymmetrical Net Change (Lig Per pulse); (5000) If zero, state method of achieving zero net change Maximum Phase Change (µC) (5000) Maximum Phase Change (µC) (5000) Maximum Current Density (Int/cm²) (5000) Maximum Power Density (Int/cm²) House Mode (i.e., pulse trans): Pulses per burst Burst Mode (i.e., pulse trans): Bursts per second Burst Mode (i.e., pulse trans): Burst density Maximum Ma	OµC Same positive and negative impulse 20µC 12,5mA/cm² 1,0mW/cm²	9µC Output copactor BµC 2,1 mA/cm ² 0,09mW/cm ²	Q _I C Output appeater 24 _I IC 3,7mA/cm ² 1,4mW/cm ²	Some positive and regative impulse Unknown 5,0mA/cm² Unknown Unknown
both phases, if asymmetrical Net Charge (Lip Per pulsa); (5000) If zero, state method of achieving zero nat charge. Maximum Phase Change (Lip(); (5000) Maximum Phase Change (Lip(); (5000)) Maximum Phase Change (Lip(); (5000)) Maximum Power Denety (Wirm*); (5000) using simpless electrode conductive surface area Burst Mode (Le, pulse trans); Pulses per burst Burst Mode (Le, pulse trans); Bursts per second Burst Mode (Le, pulse trans); Bursts duration (seconds) Burst Mode (Le, pulse trans); Burst duration (seconds)	OμC Same positive and regative impulse 20μC 12,5πWcm² 1,0mW/cm² B 2	GpC Output corporator BpC 2,1mA/cm² O,09mW/cm² 7 2	ΟμC Output oppcator 24μC 3,2mA/cm ² 1,4mW/cm ² 7 0,5 – 5	Some positive and negative impulse Unknown 5,0mA/cm² Unknown Unknown Unknown
both phases, if asymmetrical Net Change (Lip Per pulse); (5000) if zero, state method of achieving zero net change. Maleman Phase Change (µC) (5000) Maleman Phase Change (µC) (5000) Maleman Current Density (Witern') (5000) using smallest electrode conductive surface oma Burst Mode (i.e., pulse trans); Pulses per burst Burst Mode (i.e., pulse trans); Burst per second Burst Mode (i.e., pulse trans); Burst duration (seconds) Burst Mode (i.e., pulse trans); Burst duration (seconds) Burst Mode (i.e., pulse trans); Burst duration (seconds) Burst Mode (i.e., pulse trans); Duty Cybe (Line (b) t Line (c))	0µC Same positive and regative impulse 20µC 12,5mA/cm² 1,0mW/cm² B 2 100ms	OμC Output copocitor ΒμC 2.1 mA/om ⁷ 0,09mW/cm ² 7 2 87,5ms	0μC Output oppeator 24μC 3,2mA/cm² 1,4mW/cm² 7 0,5 - 5 87.5ms	Some positive and negative impulse Unknown 5,0mA/cm² Unknown Unknown Unknown Unknown Unknown Unknown
both phases, if asymmetrical Net Charge (ijc per pulsa); (5000) If sero, state method of ochieving zero net charge. Maximum Phase Charge (ijc) (5000) Maximum Phase Charge (ijc) (5000) Maximum Power Densey (Wirch*) (5000) using smallest electrode conductive authors oma Surst Mode (i.e., pulse trans); Pulses per burst Burst Mode (i.e., pulse trans); Bursts per second Burst Mode (i.e., pulse trans); Bursts per second Burst Mode (i.e., pulse trans); Burst duration (seconds)	OµC Same positive and negative impulse 20µC 12,5mA/cm² 1,0mW/cm² B 2 100ms	9µC Output corporator BµC 2,1mA/cm² 0,09mW/cm² 7 2 87,5ma 17,5%	Q _I C Output opporter 24 _I C 3,2mA/cm ² 1,4mW/cm ² 7 0,5 - 5 87,5ma 4,4% - 44%	Some positive and negative impulse Unknown 5,0mA/cm² Unknown Unknown Unknown Unknown



Biofeedback:

Characteristics/ Specifications	New Device	Predicate Device	Predicate Device
Basic Unit Chracteristics	K080950	K053434	K040849
510(k) Number			
Manufacturer	Otto Bock	Thought Technology Ltd.	Mentamove North America, LCC
Device Name, Model	STIWELL med4	Myotroc Infinity	Mentamove
Power Source(s)	Battery Pack Li-lon 11,1V	Battery Pack NiMH rechargeable	Battery Pack NiMH rechargeable
Method of Line Current Isolation	Medical Class II Power Adapter – Mascot (12,6VDC-15,1W)	Medical Class II Power Adapter (6VDC- 15W)	Battery Charger (6VDC-2,tW)
Patient Leakage Current (normal condition)	N/A (Bottery)	N/A (Battery)	N/A (Battery)
Patient Leakage Current (single fault condition)	N/A (Battery)	N/A (Battery)	N/A (Battery)
Number of Output Modes	1	0	0
Number of Output Channels	1	0	0
Number of EMG (input) Channels	2	2	1
EMG sensitivity	1µV	<0,1μV	1μV
EMG Sampling Rate	3kHz	2,048kHz	Unknown
EMG detection (bipolar/ monopolar)	Bipolar	Bipolar	Bipolar
MG range (μV)	1-2000μV	0-2000μV	2-2000μV
MG bandwidth	70-480Hz	10Hz-1kHz	Unknown
MG signal processing (eg. RMS)	AVR	RMS	Unknown
	(Average Rectified Value)	(Root Mean Square)	
Synchronous or Alternating?	N/A	N/A	N/A
Method of Channel Isolation	N/A	N/A	N/A
Regulated Current or Regulated		1 - 1	p.11.4
/oltage?	N/A	N/A	N/A
Control?	Yes	Yes	Yes
Automatic Overload Trip?	N/A	N/A	N/A
Automatic No-Load Trip?	N/A	N/A	N/A
Automatic Shut Off?	Yes (10min)	Unknown	Unknown
atient Override Control?	Yes (Stop Button)	Yes	Yes
ndicator Display: On/Off Status?	Yes	Yes	Yes
ndicator Display: Low Battery?	Yes	Yes	Yes
ndicator Display: Voltage/Current	N/A	N/A	N/A
_evel? Firmer Range [minutes]	5-30min	1-120min	Unknown
	IEC 60601-1	1	
Compliance with Voluntary Standards? (if yes, specify)	IEC 60601-1-2 IEC 60601-2-10	Unknown	Unknown
Compliance with 21 CFR 898?	Yes	Unknown	Unknown
Weight	440g	330q	Unknown
Dimensions (WxHxD) in [mm]	175x95x30	102x152x51	Unknown
lousing Material and Construction	Plastics	Plastics	Plastics
	rasics	riusics	riusius
Output Specifications		 	
Vovetorm (e.g., pulsed monophosic, piphasic)	N/A	N/A	N/A
Shape (e.g., rectangular, spike, rectified sinusoidal)	N/A	N/A	N/A
Maximum Output Voltage (500Ω)	N/A	N/A	N/A
Maximum Output Voltage (2kΩ)	N/A	N/A	N/A
Maximum Qutput Voltage (10kΩ)	N/A	N/A	N/A
Aaximum Output Current (500Ω)	N/A	N/A	N/A
Aaximum Output Current (2kΩ)	N/A	N/A	N/A
Aoximum Output Current (2kΩ)	N/A	N/A	N/A
	N/A N/A	N/A N/A	N/A N/A
ulse Width (specify units)			
requency (Hz)	N/A	N/A	N/A
or interferential modes only: Beat requency (Hz)	N/A	. N/A	N/A
or multiphasia waveforms only: lymmetrical phases?	N/A	N/A	· N/A
or multiphasic waveforms only: Phase Duration (including units);	N/A	N/A	N/A
Vet Charge (μC per pulse); (500Ω)	N/A	N/A	N/A
Maximum Phose Charge (μC) (500Ω)	N/A	N/A	N/A
Maximum Current Density [mA/cm²] 500Ω)	N/A	N/A	N/A
Maximum Power Density [W/cm²] 500Ω)	N/A	N/A	N/A
Burst Mode (i.e., pulse trains): Pulses	N/A	N/A	N/A
Burst Mode (i.e., pulse trains): Bursts		N/A	N/A
per second Burst Mode (i.e., pulse trains): Burst	N/A	N/A	N/A
duration (seconds) Burst Mode (i.e., pulse trains): Duty	N/A	N/A	N/A
Cycle [Line (b) x Line (c)] ON Time [seconds]	N/A	N/A	N/A
OFF Time [seconds]	N/A	N/A	N/A
		N/A	N/A



G **Functional and Safety Testing:**

Tests have been carried out according to the following standards:

No.	Title	Version	Comments
IEC 60601-1	Medical electrical equipment Part 1: General requirements for safety	1996-03	Medical electrical devices (Testing)
IEC 60601-1-1	Medical electrical equipment Part 1-1: General requirements for safety – Safety requirements for medical electrical systems	2002-09-01	Medical electrical devices (Testing)
IEC 60601-1-2	Medical electrical equipment Part 1-2: General requirements for safety –Electromagnetic compatibility – requirements and tests	2001	EMC (Testing)
IEC 60601-1-4	Medical electrical equipment Part 1-4: General requirements for safety – Programmable electrical medical systems	2001-06-01	Programmable Systems
IEC 60601-2-10	Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	2003-04	Medical electrical devices; EMC (Testing)
IEC 721-3-2	Classification of Environmental Conditions Part 3-2: Classes of Influencing Factors - Transport	1981	Transport (Testing)
ISO 2248	Packaging - Complete, filled transport packages - Vertical impact test by dropping	1985	Transport (Testing)
ISO 2876	Packaging - Complete, filled transport packages - Rolling test	1985	Transport (Testing)
IEC 60512-8	Electromechanical components for electronic equipment; basic testing procedures and measuring methods Part 8: Connector test (mechanical) and mechanical test on contacts and terminations	3.0/1994- 05	Specific sections were used for verification testing
IEC 60512-9	Electromechanical components for electronic equipment; basic testing procedures and measuring methods Part 9: Miscellaneous tests	2.0/1992- 05	Specific sections were used for verification testing
IEC 68-1 +Corr.+A1	Environmental testing Part 1: General and Guidance	1998	Specific sections were used for verification testing
IEC 68-2-1 +A1+A2	Environmental testing Part 2-1: Tests, Tests A: Cold	1994	Specific sections were used for verification testing



No.	Title	Version	Comments
IEC 68-2-2	Environmental testing	1994	Specific sections
+IEC68-2-2A+A2	Part 2-2: Tests, Tests B: Dry heat		were used for
			verification testing
IEC 68-2-30	Environmental testing - Part 2-30: Tests	2000	Specific sections
	- Test Db: Damp heat, cyclic (12 h + 12		were used for
	h cycle)		verification testing
IEC 68-2-33	Environmental testing - Part 2-33: Tests.	2000	Specific sections
	Guidance on change of temperature		were used for
	tests		verification testing
IEC 68-2-36	Environmental testing	1973	Specific sections
	Part 2-36, Tests Fdb: Vibrations, noise		were used for
	(broadband), repeatability: medium		verification testing
IEC 68-2-78	Environmental testing	2001	Specific sections
	Part 2-78: Tests, Test Cb: Damp heat,		were used for
	steady state, primarily intended for		verification testing
	devices		
21 CFR 898	Performance Standard for electrode	1997	Electrical safety
	lead wires and patient cables		(Testing)

In addition to tests according to the above mentioned standards several functional and safety tests defined by the manufacturer have been conducted.



H Indications for use:

The STIWELL med4 is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

As a powered muscle stimulator the STIWELL med4 is indicated for the following conditions:

- Relaxation of muscle spasm
- · Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- · Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

As a transcutaneous electrical nerve stimulator for pain relief the STIWELL med4 is indicated for the following conditions:

- Symptomatic relief and management of chronic (long-term), intractable pain
- Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain

As a biofeedback device the STIWELL med4 is indicated for the following conditions:

· Biofeedback, relaxation and muscle re-education purposes

As an external functional neuromuscular stimulator the STIWELL med4 is indicated for the following conditions:

· Helps to relearn voluntary motor functions of the extremities

As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions:

- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the
 following results may improve urinary control: Inhibition of the detruser muscles through
 reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles

I Conclusion:

The STIWELL med4 stimulation device is safe and effective for its intended use. The STIWELL med4 is substantially equivalent to the predicate devices.

J Date summary submitted:

21st January 2008

APR - 2 2009





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Otto Bock, Austria GmbH % W.F. Jackson Associates, Ltd Mr. William Jackson 2247 Jennifer Lane North St. Paul, Minnesota 55109-2851

Re: K080950

Trade/Device Name: STIWELL med4 Regulation Number: 21 CFR 890.5850

Regulation Name: Powered muscle stimulator

Regulatory Class: II

Product Code: IPF, GZI, KPI, GZJ, HCC

Dated: March 2, 2009 Received: March 25, 2009

Dear Mr. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080950

Device Name: STIWELL med4

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rescription Use X	AND/OR	Over-The-Counter Use
Per 21 CFR 801 Subpart D)		(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Maluation (ODE)

(Division Sign-Off)

Division of General, Restorative,

and Neurological Devices

510(k) Number K080950

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